



## Prospective, Randomized, Controlled, Multicenter Study

Schmidt et al. *Journal of Neurosurgery: Spine*. Epub ahead of Print, January 26, 2018.

*The primary goal of spinal stenosis surgery is to produce a sustainable treatment outcome without requiring reoperations or further epidural interventions.<sup>^</sup>*

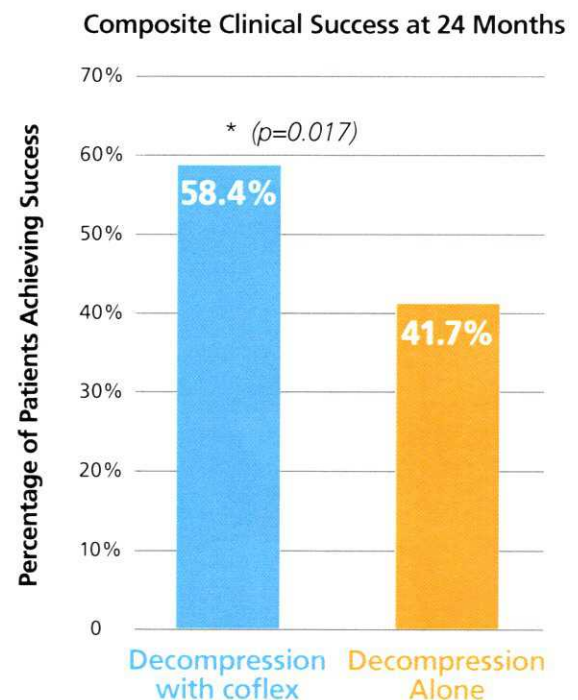
– Sven Schmidt, MD, Joerg Franke, MD, Michael Rauschmann, MD, Dieter Adelt, MD, Matteo Mario Bonsanto, MD, and Steffen Sola, MD

**Study Purpose:** To compare Decompression Alone (DA) to decompression with coflex Interlaminar Stabilization

**Study Design:** 225 patients, 7 sites, 1:1 randomization, evaluations at pre-op, 3 months, 12 months, 24 months; 91% follow up at 2 years

### Study Conclusions:

- 1. coflex is statistically superior compared to decompression alone for Composite Clinical Success\* ( $p=0.017$ )**
- 2. Interlaminar Stabilization with coflex increases walking distance, decreases compensatory pain management, and maintains foraminal height; thereby extending the durability and sustainability of a decompression procedure out to 2 years**



### Additional Key Study Results at 24 Months:

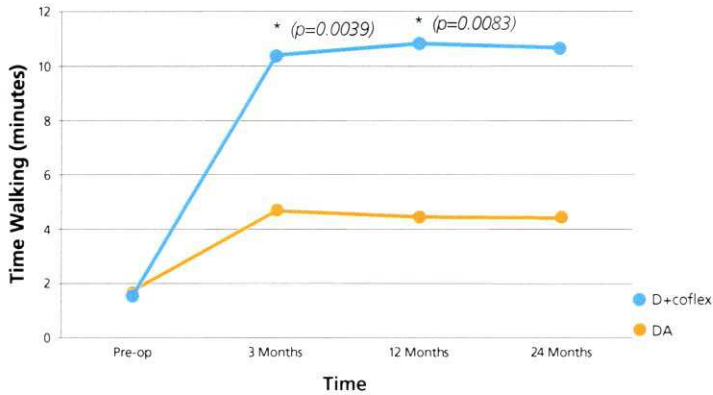
- coflex had 2.4x more improvement in walking distance measurements compared to DA ( $p=0.062$ )
- DA had a 1.75x higher risk for secondary intervention compared to coflex ( $p=0.055$ )
- DA experienced 228% more subsequent epidural steroid injections compared to coflex ( $p=0.010$ )
- DA had a sooner time to epidural steroid injections compared to coflex ( $p=0.0065$ )
- coflex maintained foraminal height and posterior disc height better than DA ( $p<0.001$ )

<sup>^</sup>European Study of Coflex and Decompression Alone. Prospective, Randomized, Controlled, Multicenter Study With Two-year Follow-up to Compare the Performance of Decompression With and Without Interlaminar Stabilization; Sven Schmidt, MD, Joerg Franke, MD, Michael Rauschmann, MD, Dieter Adelt, MD, Matteo Mario Bonsanto, MD, and Steffen Sola, MD. *Journal of Neurosurgery: Spine*. Epub ahead of Print, Jan 26, 2018

\*Composite Clinical Success (CCS): Overall trial success was based on a composite endpoint; a combined outcome measure in which all four components must be met: 1) ODI success with improvement > 15 points; 2) survivorship with no secondary surgical interventions or lumbar injections; 3) neurological maintenance or improvement without worsening; and 4) no device- or procedure-related severe adverse events

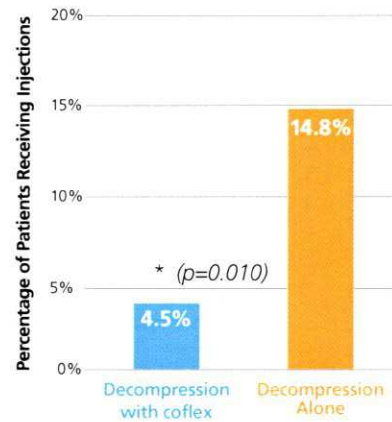
Decompression Alone patients are **1.75x** more likely to require secondary intervention (reoperation and/or epidural steroid injection) compared to coflex patients

### Walking Distance Median Improvement



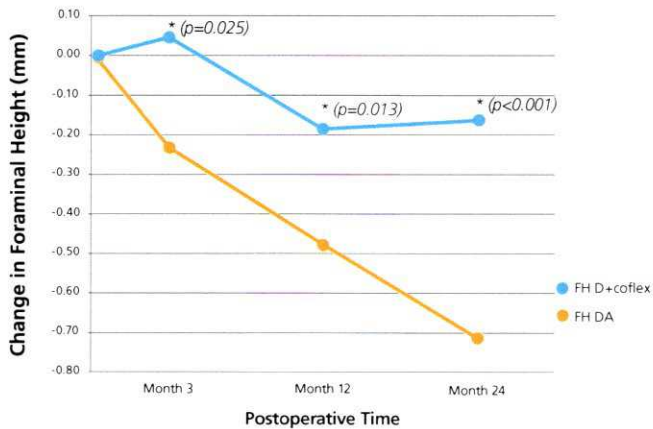
coflex patients improved their walking distance more than 5 times as much compared to before they were treated. Decompression Alone patients only improved 2 times as much.

### Overall Epidural Steroid Injections



There were 2.28 times more epidural steroid injections in the Decompression Alone group compared to the coflex group.

### Foraminal Height Change Over Time



### Posterior Disc Height Change Over Time

